

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

U-A PD

To:

Amersham Biosciences AB
Patents Department
Björkgatan 30
751 84 Uppsala
Sweden

06-MAY-2006 ✓

C.N R.P. ✓

A.K

8/3106

PU0418-PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

07-03-2006

Applicant's or agent's file reference

PU0418-PCT ✓

REPLY DUE

within 60 days from
the above date of mailing

International application No.

PCT/SE 2005/000467 ✓

International filing date (day/month/year)

31-03-2005 ✓

Priority date (day/month/year)

02-04-2004 ✓

International Patent Classification (IPC) or both national classification and IPC

See Supplemental Box

Applicant

Amersham Biosciences AB et al

1. ☒ The written opinion established by the International Searching Authority:

☒ is
 ☐ is not

 considered to be a written opinion of the International Preliminary Examining Authority.
2. This second (first, etc.) opinion contains indications relating to the following items:

☒ Box No. I Basis of the opinion
☐ Box No. II Priority
☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐ Box No. IV Lack of unity of invention
☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐ Box No. VI Certain documents cited
☒ Box No. VII Certain defects in the international application
☐ Box No. VIII Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 02-08-2006

Name and mailing address of the IPEA/SE

Patent- och registreringsverket

Box 5055

S-102 42 STOCKHOLM

Facsimile No. 46 8 667 72 88

Form PCT/IPEA/408 (cover sheet) (April 2005)

Authorized officer

Jens Waltin/ELY

Telephone No. 46 8 782 25 00

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

PCT/SE 2005/000467

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: **Cover sheet**

International patent classification (IPC)

B01D 15/18 (2006.01)

C07K 1/36 (2006.01)

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE 2005/000467

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____,
which is the language of a translation furnished for the purposes of:
☐ international search (Rules 12.3(a) and 23.1(b))
☐ publication of the international application (Rule 12.4(a))
☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):

- ☒ the international application as originally filed/furnished
☐ the description:
pages _____ as originally filed/furnished
pages _____ received by this Authority on _____
pages _____ received by this Authority on _____
☐ the claims:
pages _____ as originally filed/furnished
pages _____ as amended (together with any statement) under Article 19
pages _____ received by this Authority on _____
pages _____ received by this Authority on _____
☐ the drawings:
pages _____ as originally filed/furnished
pages _____ received by this Authority on _____
pages _____ received by this Authority on _____
☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE 2005/000467

Box No. V Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-4, 8, 10-11</u>
	Claims	
Inventive step (IS)	Claims	<u>1-4, 8, 10-11, 15-28</u>
	Claims	
Industrial applicability (IA)	Claims	
	Claims	

2. Citations and explanations:

Most relevant document cited in the International Search Report:

D1: US 3 869 436 A

D1 relates to the fractionating of plasma proteins by ion-exchange chromatography. The method comprises:

- precipitating the globulins in the plasma with poly(ethylene glycol) (PEG),
- centrifuging out all of the precipitate from the remaining solution,
- dissolving the precipitate in sodium acetate-acetic acid,
- adsorbing the globulins from the dissolved precipitate on a cation-exchanger,
- precipitating the eluate with PEG,
- dissolving the precipitate in phosphate buffer, and
- adsorbing the globulins from the dissolved precipitate on an anion-exchanger.

The method according to claims 1-4, 8 and 10-11 lacks novelty in view of D1.

The features of claims 15-17, regarding the design of the ion-exchange matrix, are known per se. They are considered to be merely some of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill,

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WRITTEN OPINION OF THE
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PCT/SE 2005/000467

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: BOX V

in order to solve the problem posed. Therefore, the invention according to claims 15-17 is considered to lack an inventive step.

The invention according to the independent claims 20 and 25 relates to a method for isolating an antibody compound from a liquid, comprising contacting the liquid, in the presence of a non-ionic polyether, with an ion-exchange chromatography matrix.

The method according to claim 20 differs from the subject matter of D1 in that the conductivity is specified to equivalent to 200 mM NaAc. NaAc is mentioned in D1 but the conductivity is not specified. However, this difference is not considered inventive. Thus, claim 20 and the dependent claims 21-24 lack an inventive step.

In independent claim 25, the design of the ion-exchange matrix is specified. For the same reasons as set out above, in connection with claims 15-17, the subject matter of claims 25-27 is considered to lack an inventive step.

Claims 18-19 and 28 relate to kits with separate compartments intended for antibody isolation. Such kits are well-known to a person skilled in the art and this solution has already been applied for the same purpose in similar contexts. Therefore, the subject matter of claims 18-19 and 28 is not considered inventive.

**WRITTEN OPINION OF THE
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International application No.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

In claims 7-9, it seems that the words "according to any one of the preceding steps" should be replaced by "according to any one of the preceding claims".